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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | ATTORNEY DOCKET NO. CONFIRMATION NO. |  |  |
|--|-------------|----------------------|---------------------|--------------------------------------|--|--|
| 10/734,625   | 12/15/2003  | Geoffrey Allan       | 1633.0400002        | 2541                                 |  |  |
| 26111 75900 (776962010)<br>STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.<br>1100 NEW YORK AVENUE, N.W.<br>WASHINGTON, DC 20005 |             |                      | EXAM                | EXAMINER                             |  |  |
|  |             |                      | FAY, ZOHREH A       |                                      |  |  |
|  |             |                      | ART UNIT            | PAPER NUMBER                         |  |  |
|  |             |                      | 1612                |                                      |  |  |
|  |             |                      |                     |                                      |  |  |
|  |             |                      | MAIL DATE           | DELIVERY MODE                        |  |  |
|  |             |                      | 07/08/2010          | PAPER                                |  |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

| Application No. | Applicant(s) |
|-----------------|--------------|
| 10/734,625      | ALLAN ET AL. |
| Examiner        | Art Unit     |
| ZOHREH A. FAY   | 1612         |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS.

WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
- after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to repty within the set or extended period for repty will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any

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| Status                               |   |   |
|--------------------------------------|---|---|
| 2a)⊠                                 | Responsive to communication(s) filed on <u>01 April 2010</u> .  This action is <b>FINAL</b> .  2b   This action is not Since this application is in condition for allowance except for closed in accordance with the practice under <i>Ex parte Qual</i>  | r formal matters, prosecution as to the merits is   |
| Disposit                             | tion of Claims  |   |
| 5)□<br>6)⊠<br>7)□                    | Claim(s) <u>4-17</u> is/are pending in the application.  4a) Of the above claim(s) <u>6,7 and 11-13</u> is/are withdrawn fro Claim(s) is/are allowed.  Claim(s) <u>5,8,9,14-17</u> is/are rejected.  Claim(s) is/are objected to.  Claim(s) are subject to restriction and/or election req  |   |
| Applicati                            | tion Papers   |   |
| 10)                                  | The specification is objected to by the Examiner.  The drawing(s) filed on  | held in abeyance. See 37 CFR 1.85(a).  If the drawing(s) is objected to. See 37 CFR 1.121(d). |
| Priority ι                           | under 35 U.S.C. § 119   |   |
| a)                                   | Acknowledgment is made of a claim for foreign priority unde  □ All b □ Some * c □ None of:  1.□ Certified copies of the priority documents have been  2.□ Certified copies of the priority documents have been  3.□ Copies of the certified copies of the priority documen  application from the International Bureau (PCT Rule  See the attached detailed Office action for a list of the certifie | received. received in Application No Is have been received in this National Stage 17.2(a)).   |
|                                      |   |   |
| Attachmen                            |   | _   |
| 2) Notice<br>3) Information<br>Paper | ice of Draftsperson's Patent Drawing Review (PTO-948) matter Disclosure Statement(s) (PTO/S5/08) er No(s)/Mail Date   | Interview Summary (PTO-413)   Paper No(s)/Mail Date.  |
| S. Patent and T                      | Trademark Office  |   |

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Claims 4-17 are pending in the instant application.

Claims 5, 8-10 and 14-17 are presented for examination.

The amendments and remarks filed on April 1, 2010 have been received and entered.

Claims 5, 8-10 and 14-17 are rejected under 35U.S.C. 112 first paragraph for the reasons set forth on pages 2-5 of the office action of June 4, 2009.

Claims 5, 8-10 and 14-17 are rejected under 35 U.S.C. 112 second paragraph for the reasons set forth on page 2 of the office action of December 1, 2009.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 4, 5, 8 and 14-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Shiohara et al. (US 2004/0176308).

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Shiohara et al. teach the use of phenyl pyrazoline derivatives for the treatment of diseases associated with hyperglycemia, such as hypertriglyceridemia. See the abstract and claim 7. The use of the secondary components such as, antidiabetic compounds, anti-hypertensive compounds and lipid lowering medications are taught in claim 13. The claimed concentrations are taught in Para [0109].

Applicant's arguments and remarks regarding the 112 first paragraph and 112 second paragraph have been noted. It is the examiner's position that there is no evidence that there is any per se structure/function relationship between the disclosed claimed lipoxygenase inhibitors, such as a phenyl pyrazoline derivative and any others that might be found using the claimed method. Structural identifying characteristics of group of lipoxygenase derivatives as claimed in claim 5 are not disclosed.

Applicant is reminded that in the absence of established correlation between structure and function of the claimed derivatives, one can not predict if the activity is due the compound being a phenyl pyrazoline derivative having 5-lipoxygenase inhibitory activity or another mechanism. Furthermore, the term "derivative" is indefinite, because it is unclear how far one can deviate from the parent compound without the derivative being so far removed therefrom to be a completely different compound.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on April 1, 2010 prompted the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZOHREH A. FAY whose telephone number is (571)272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ZF

/Zohreh A Fay/ Primary Examiner, Art Unit 1612